



Plaintiffs responded with a rather startling admission – that exposure to lead and/or lead-related injury are not at issue in this case. (Resp. pp. 1, 4)<sup>1</sup> This admission vividly demonstrates the value of the Rule 16 process as it sets the stage for an “elimination of frivolous claims” under Rule 16(c)(1).

Rule 16(c) states in pertinent part:

(c) At any conference under this rule consideration may be given, and the court may take appropriate action, with respect to

(1) the formulation and simplification of the issues, including the elimination of frivolous claims and defenses;

...

(16) such other matters as may facilitate the just, speedy, and inexpensive disposition of the action

As the Advisory Committee Notes explain:

The reference in Rule 16(c)(1) to “formulation” is intended to clarify and confirm the court’s power to identify the litigable issues. It has been added in the hope of promoting efficiency and preserving judicial resources by identifying the relevant issues prior to trial, thereby saving time and expense for everyone. See generally *Meadow Gold Prods. Co. v. Wright*, 278 F.2d 867 (D.C.Cir. 1960). The notion is emphasized by expressly authorizing the elimination of frivolous claims or defenses at a pretrial conference. There is no reason to require that this await a formal motion for summary judgment. Nor is there any reason for the court to wait for the parties to initiate the process called for in Rule 16(c)(1).

Plaintiffs now contend that the Complaints in both *Ramos* and *Scalia* (the “Complaints”) only attempt to state claims related to consumer fraud. But this re-styling of the Complaints (which is wholly inconsistent with express allegations of lead exposure, ingestion and poisoning, *Ramos* Compl. ¶¶6, 65, 79, 81, 86-97) does not avoid the need to prove exposure to sustain all counts of the Complaints.

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<sup>1</sup> Also significant is Plaintiffs’ continued failure to simply identify the Medela product at issue.

The gravamen of Plaintiffs' consumer fraud claim is that Medela told consumers that its [as yet unidentified] product was safe, and it was not safe. But what is unsafe or "defective and inherently dangerous" about a product which does not expose the user to lead? Where is the legal duty to disclose lead content where use of the product does not expose consumers to lead? And how can a product "create[] a high risk of adverse health effects which can cause extraordinary suffering and even death" (*Ramos* Compl. ¶80) without exposure to lead? And, finally, how can a manufacturer be unjustly enriched when it acted in an entirely lawful manner and no one was harmed by its product?

Medela's bottle cooler carriers are fully functional and safe for their intended use. Plaintiffs admit that they have no evidence to the contrary. Instead of withdrawing claims for which they have no evidentiary support, Plaintiffs now argue that their injury is speculative – that if the Plaintiffs had known that the [unidentified] bottle cooler carrier had any lead content, they would not have purchased the bottle cooler carrier. Such a speculative claim cannot, however, sustain any of the counts in the Complaints because Plaintiffs cannot establish the requisite elements of their claims with no evidence that the product is not safe for its intended use, *i.e.* no evidence of human contact with lead by use of the bottle cooler carrier.

Significantly, even Plaintiffs admit that grounding all of their claims of injury on a desire for replacement of the bottle cooler carriers, or a refund of the cost of that product, effectively "moots" their claims and makes continued litigation against Medela "unlikely" (Resp. p. 6). Medela has offered to replace or provide refunds for bottle cooler carriers if the purchaser chooses to seek either option; and the replacement offer was made *before* the Complaints were filed. (See ¶5 of the *Ramos* Complaint and ¶5 of the *Scalia* Complaint). Thus, in Plaintiffs' words, the Complaints were "moot" before they were filed.

Additionally, Plaintiffs admitted in Court and again in their Response that this is *not a toxic tort case*<sup>2</sup>. Therefore, all demands for toxic tort remedies, *e.g.* medical monitoring, must be stricken from the Complaints.

Accordingly, Medela respectfully submits that the Court could proceed to dismiss all claims against it under Rule 16(c)(1) as frivolous or, in Plaintiffs' words, "moot". At a minimum, all claims for medical monitoring should be struck and a Rule 16(c)(12) order issued requiring Plaintiffs to identify the Medela product at issue and to provide factual and expert detail for their claims of injury, including exposure and lead-related injury.

**I. EXPOSURE IS A CENTRAL ELEMENT OF PLAINTIFFS' *PRIMA FACIE* CASE OF CONSUMER FRAUD.**

While Plaintiffs claim that "exposure" has no bearing on this case, their Complaints are to the contrary. For example, Plaintiffs devote an entire section to an "Overview of Lead Poisoning" in which they acknowledge repeatedly that an individual must be "exposed" to lead through "ingestion" in order for the lead to "lodge[] in the bone or skeletal structure of the body" or "move into the bloodstream and cause significant difficulties." *Ramos* Compl. ¶¶18-27) And "poisoning" requires, among other things, exposure. Said another way, without exposure, there can be no poisoning.<sup>3</sup> Similarly, Plaintiffs contend that "Plaintiffs' children and the children of the [putative] Class have been significantly exposed to a known hazardous

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<sup>2</sup> At the Presentation conference on June 26, 2008, plaintiffs' counsel stated "We are not alleging actual exposure or personal injury. This is not a personal injury case. This is not a products liability case." (6: 21-23) Again, "This is not a toxic tort case." (7:3).

<sup>3</sup> This is consistent with the Black's Law Dictionary (5<sup>th</sup> ed.) definition that Plaintiffs themselves provide (Resp. p. 4, fn. 1) which provides the following definition of "expose": "to place in a position where the object spoken of is open to danger, or where it is near or accessible to anything which may affect it detrimentally: as, to "expose" a child or to expose oneself or another to a contagious disease or to a danger or hazard of any kind." In the absence of exposure, there can be no danger or hazard.

substance [lead]”, and that “as a result of such exposure, the children are at an increased risk of being poisoned by lead.” (*Ramos* Compl. ¶6, see also ¶¶65, 79, 81, 86-97) Or later, in attempting to define the areas of commonality, Plaintiffs assert that common questions include “c. Whether as a result of Defendant’s negligent and reckless conduct, children have been significantly exposed to a known hazardous substance.” (*Ramos* Compl. ¶53).

These numerous allegations notwithstanding, in their Response, Plaintiffs reverse course, admitting that “actual exposure is not a necessary element of Plaintiff’s claims” (Resp. p. 1); “Plaintiffs did not allege actual exposure to lead in their Complaint,” (Resp. p. 4); “Each of [Plaintiffs’ claims] seek damages resulting from the purchase of the product itself; none of them require that Plaintiffs demonstrate actual exposure to lead in Medela’s products” (*Id.*) In essence, they are now saying that in preparing the Complaints, they used the term “exposure” in a colloquial and not a technical fashion (*Id.*). In doing so, Plaintiffs concede that that they have no evidentiary support for allegations of lead exposure or claims of lead-caused injury, maintaining that such a showing is unnecessary as a matter of law because their case is solely and exclusively predicated on the mere presence of lead in the product.

But the issue, of course, is not how Plaintiffs intended to use the term “exposure” in the Complaints nor whether they could have used another term in its place—it is what Plaintiffs must prove to make a *prima facie* case. To make their statutory case in their First Count for consumer fraud, Plaintiffs must establish that Medela made an untrue statement. *Sklodowski v. Countrywide Home Loans, Inc.*, 358 Ill.App.3d 686, 703 (2005). The alleged untrue statement is that “they continue to market products as “safe” when in fact they are not safe and contain lead.” (*Ramos* Compl. ¶40) In the Second Count, “Breach of Implied Warranty,” Plaintiffs allege that Medela’s bottle cooler carriers are “defective and inherently

dangerous” ... “are not able to function in their ordinary capacities and were therefore not merchantable at the times they were sold.” (*Ramos* Complt. ¶73) In their Third Count, “Negligence,” Plaintiffs allege that unidentified Medela bottle cooler carriers “created a high risk of adverse health effects which can cause extraordinary suffering and even death.” (*Ramos* Complt. ¶80). Plaintiffs’ Fourth Count, “Unjust Enrichment” is based on conclusory allegations of unspecified unlawful conduct. But Plaintiffs have no evidentiary support for any of their inflammatory allegations of an unsafe product.

Plaintiffs’ assertion that their claims are “already well supported” by CEH lead content data (Resp. p. 6) demonstrates a glaring lack of appreciation of the difference between lead *content* in a product and potentially dangerous *exposure* to lead in that product. Apparently, Plaintiffs have erroneously assumed that embedded lead content guarantees exposure to lead or some type of harm to the user of the product or the user’s child. But that assumption is invalid and improper. As discussed in our Opening Brief, lead exposure requires human contact with lead. “Exposure to a chemical is the contact of that chemical with the outer boundary [of the human body].” *Guidelines on Exposure Assessment*, 57 Fed. Reg. 22888, 22891 (May 29, 1992). For example, computer monitors contain substantial quantities of lead but an individual’s use of a monitor does not equate to that person’s contact with lead. *i.e.* lead exposure, because the lead within the monitor is inaccessible to the user. Without actual contact with the lead, there can be no harm from lead in a product. Therefore, Plaintiffs must show evidence of lead *exposure*, not merely lead *content*, to sustain the claims in the Complaints that Medela somehow misled consumers.

The Court could, for the reasons we have explained, enter an order pursuant to Rule 16(c)(12) requiring Plaintiffs to identify the Medela product at issue and to produce factual

and expert affidavits making a *prima facie* case on exposure. But given Plaintiffs' admissions that they have no evidence of exposure, the "frivolous claims" of the Complaints should be eliminated, resulting in a complete dismissal of the Complaints under Rule 16(c)(1).

Plaintiffs' further admission that Medela's replacement/refund offer makes continued litigation with Medela unlikely and "renders Medela's motion moot" (Resp. p. 6) further supports complete dismissal of both Complaints. Plaintiffs referenced the replacement offer in the Complaints (*Ramos* and *Scalia* Complt. ¶5). Thus, to paraphrase Plaintiffs, the Complaints were "moot" before they were filed, and Plaintiffs should not be allowed to proceed with litigation under those Complaints.

**II. PLAINTIFFS HAVE ABANDONED THEIR CLAIM FOR DIAGNOSTIC TESTING DAMAGES AND THE CLAIMS FOR THESE DAMAGES SHOULD BE STRICKEN.**

In their Complaints, Plaintiffs ask the Court to enter an order requiring defendants to pay for medical monitoring: "damages in the amount of monies paid or to be paid for lead testing of the children exposed to the VPBP," . . . . (*Ramos* Complt. ¶21)

Those states which permit plaintiffs to recover medical monitoring costs in toxic tort cases require plaintiffs to "establish that he or she came in contact with the chemicals produced by defendants." (Op. Br. pp. 7-9, quoting from *Donaldson v. Cent. Ill. Pub. Serv. Co.*, 199 Ill. 2d 63, 91 (2002) Here, where Plaintiffs admit they are not making toxic tort claims and have no evidence that Plaintiffs or their children came in contact with lead (Resp. pp. 1, 2, 3), the law provides no basis for toxic tort damages in the form of medical monitoring.

Plaintiffs' Response suggests that they have dropped their claims for medical monitoring costs. Where there is no lead exposure or lead-related injury – as Plaintiffs concede here – there can be no imposition of medical monitoring costs on Medela relating to exposure to lead from its bottle cooler carriers.

As explained in our Opening Brief (p. 9):

Causation is a core element in any tort case. As the Illinois Supreme Court explained in *Smith v. Eli Lilly and Co.*, 137 Ill. 2d 222, 232 (1990), “In a negligence action, this causation-in-fact requirement entails a ‘reasonable connection’ between the act or omission of the defendant and the damages. *Cf.*, *Lewis v. Lead Industries Ass’n*, 342 Ill. App. 3d 95, 103 (2003). A “reasonable connection” is particularly important as a threshold matter in a case like this, in which the chemical at issue is truly ubiquitous.

In light of Plaintiffs’ admission that they have no evidence of exposure to lead or lead-related injuries from Medela’s bottle cooler carriers, they cannot prove that Medela’s bottle cooler carriers “caused” any lead poisoning, and thus cannot recover medical monitoring costs from Medela in this case. It therefore is appropriate for the Court to strike all claims for the costs of medical monitoring as being frivolous pursuant to the powers granted by Rule 16(c)(1).

### **III. CONCLUSION.**

Plaintiffs admit that only consumer fraud claims remain in this consolidated case. Those claims cannot be sustained without evidence of exposure, and Plaintiffs admit they have none. Further, Plaintiffs concede that all remaining claims are “moot” and that their litigation against Medela should not continue. Therefore, Medela respectfully requests that the Court dismiss the Complaints pursuant to Rule 16(c)(1). Alternatively, Medela requests that the Court enter the requested Order pursuant to Rule 16(c)(12) and strike all claims for medical monitoring costs.



Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 24<sup>th</sup> day of July 2008, I caused a copy of the foregoing document, DEFENDANT MEDELA'S REPLY IN SUPPORT OF MOTION FOR ENTRY OF A CASE MANAGEMENT ORDER PURSUANT TO RULE 16(c)(12), to be filed electronically. Notice of this filing will be sent to the attorneys listed immediately below by operation of the Court's ECF system, which notice shall constitute service pursuant to Local Rule 5.9. Parties may access this filing through the Court's system.

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